DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2001

Mr. Ademola Akinmade
President
First Scientific Limited
7 Roseheyworth Business Park
Abertillery
Blaenau Gwent, Wales,
UNITED KINGDOM

Re: K011295
Trade/Device Name: Restore-PF VIC; Restore-PF VLC Capsule
Regulation Number: 872.3690
Regulatory Class: II
Product Code: EBF
Dated: June 14, 2001
Received: June 14, 2001

Dear Mr. Akinmade:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011295

1 OF 4

510(k) Number (if known): K011295

Device Name: Restore-pf vlc; Restore-pf vlc Capsule

Indications for Use:

3.2.1. *RESTORE-pf vlc Hand mix version*

FSL RESTORE VLC is a light cured reinforced glass-ionomer cement designed for the adhesive restoration of teeth. It features visible light curing for ease of operation. Light curing allows extended working time and quick setting on demand. *FSL RESTORE VLC* exhibits strong ionomer bond to teeth.

FEATURES

- Fluoride release
- Light cured
- Excellent chemical adhesion
- Good biocompatibility
- Simplified clinical procedure
- Excellent "dark cure" properties

Good mechanical properties

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011295

(Optional Format 1-2-96)

K011295
2 of 4

510(k) Number (if known): K011295

Device Name: Restore-pf vlc; Restore-pf vlc Capsule

Indications for Use:

CLINICAL USES
- Class III and V restorations, and particularly the restoration of cervical erosions and root surface caries
- Restoration of deciduous teeth
- Core build-up

CONTRAINDICATIONS
Pulp capping

DIRECTIONS FOR USE
1. TOOTH PREPARATION
- Clean the cavity preparation with pumice and water. Rinse thoroughly and dry. Do not desiccate
- You can use bonding agent or aqueous poly(acrylic acid) solution to maximise adhesion. Follow manufacturers' instructions. For FSL Bonding agent, this involves brushing the one-step formulation generously onto the enamel and dentine with agitation for 30 seconds. Dry cautiously with oil-free air for 15 seconds. Cure the bonding agent coating with a dental halogen light for 20 seconds. Apply second layer and cure treat as before.
- Apply calcium hydroxide liner to deep areas of possible pulpal exposure

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner
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Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011295

K011295
3 of 4

510(k) Number (if known): K011295

Device Name: Restore-pf vlc; Restore-pf vlc Capsule

Indications for Use:

3.2.2. *RESTORE-pf vlc Capsule version*

FSL RESTORE-pf VLC is a light cured reinforced glass-ionomer cement designed for the adhesive restoration of teeth. It features visible light curing for ease of operation. Light curing allows extended working time and quick setting on demand. *FSL RESTORE VLC* exhibits strong ionomer bond to teeth.

FEATURES

- Fluoride release
- Light cured
- Excellent chemical adhesion
- Good biocompatibility
- Simplified clinical procedure
- Excellent "dark cure" properties
- Good mechanical properties

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(Optional Format 1-2-96)

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510(k) Number K011295

510(k) Number (if known): K011295

Device Name: Restore-pf vlc, Restore-pf vlc Capsule

Indications for Use:

CLINICAL USES
- Class III and V restorations, and particularly the restoration of cervical erosions and root surface caries
- Restoration of deciduous teeth
- Core build-up

CONTRAINDICATIONS
Pulp capping

DIRECTIONS FOR USE
1 TOOTH PREPARATION
- Clean the cavity preparation with pumice and water.Rinse thoroughly and dry. Do not dessicate
- You can use aqueous poly(acrylic aacid) conditioner or water-based dentine bonding agent to maximise bonding to dentine.
- Apply calcium hydroxide liner to deep areas of possible pulpal exposure

2. CAPSULE ACTIVATION
- Follow the instructions contained for capsule activation contained in the leaflet included with the product.
- Keep capsules away from sunlight

3. FILLING AND FINISHING
- After filling, form the contour with an instrument. A celluloid strip or matrix may be used and removed after the material has set.
- Cure for 20s with a visible light curing device. If a layer of over 2 mm is intended, use a layering technique
- After the cement has set, perform finishing under water spray.

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